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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/357,737 | 07/19/1999 | ALESSANDRO SETTE | 18623-01400 | 9669 |

28393 7590 04.17.2003

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| EXAMINER |
|---|
| SCHWADRON, RONALD B |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | 28 |

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/357,737 | Sette et al. |
| **Examiner** | **Art Unit** |
| Ron Schwadron, Ph.D. | 1644 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 77-97, 122-141, 166-186, 205-246 is/are pending in the application.

4a) Of the above, claim(s) 77-97, 122-141, 167, 169, 171-176, 179, 181-~~246~~186, 205-246 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 166, 168, 170, 177, 180, 178 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4) ☐ Interview Summary (PTO-413) Paper No(s).
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Applicant's election with traverse of Group I, in Paper No. 25 is acknowledged. The traversal is on the ground(s) that are stated in said paper. Regarding applicants comments about serious burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the search of additional Groups. Applicants comments regarding rejoining of withdrawn process claims in the event of allowable product claims have been noted. There are currently no allowed product claims in the instant application.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 205-246 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 25

3. Applicant's election without traverse of the species GVAGALVAFK and T helper epitope in Paper No. 25 is acknowledged.

4. Claims 77-165,167,169,171-176,179,181-204 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 25.

5. Claims 166,168,170,177,178,180 are under consideration. Claims 98-121,142-165,187-204 have been cancelled.

6. Applicants need to update the status of all US applications disclosed in the specification.

7. Drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 178,180 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed pharmaceutical compositon or vaccine. The specification does not disclose how to use the instant invention for the in vivo treatment of HCV infection in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of HCV infection in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment of HCV infection in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

*The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:*

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .*

*35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367,*

*1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.*

*We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:*

*(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.*

*Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").*

Regarding Wands factors 4,5,7,8, the claimed inventions are drawn to a pharmaceutical composition that can be used to treat HCV infection and a vaccine for HCV. The substantial/real life use for the claimed inventions are preventing and treating HCV infection. Liang et al. disclose that development of an effective HCV vaccine is not imminent (see abstract). Thus, there is no current HCV vaccine and an expert in the field is stating that based on his assessment of the state of the art that a successful HCV vaccine is not imminent. The claimed pharmaceutical composition would function as a vaccine. Thus, the state of the art is that it is highly unpredictable whether any particular HCV derived peptide could used as a vaccine/pharmaceutical composition to treat HCV in humans. As per Wands factor (8), the claimed inventions are used for preventing and treating HCV infection.

Regarding Wands factors 1-3, the specification discloses experimental data indicating that a response to the peptide recited in the claims is found in some human patients that are HCV infected (see Table XXXI). However, the presence of a response to a particular HCV peptide in patient does not indicate that said peptide can be used as vaccine. Liang et al. teach:

"Finally, the cellular immune response is a double-edged sword. An immune response that is ineffective in clearing HCV infection may be more harmful to the liver, causing chronic inflammation, hepatocellular injury, and, over several decades, liver fibrosis and cirrhosis." (page 2998, first column).

Thus, use of a particular peptide for treatment/prevention of HCV infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides data, wherein the art recognizes that such data is not predictive of whether the claimed invention could be used in vivo in humans to treat/prevent HCV infection. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.). With regards to Wands factor 7, Liang et al. disclose that an effective HCV vaccine would require components that stimulate helper T cells, especially Th1 and also would require a component that stimulates antienvelope antibody (see page 303, second column). The claimed invention appears to contain neither of the above. Thus, it appears unpredictable as to whether the claimed invention could be used an HCV vaccine. In addition, the elected species only binds MHC
of a particular set of alleles (as disclosed in the specification) and therefore said peptide would have no effect in individuals which express MHC alleles which do not bind said peptide.

Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

10. Claim 170 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the peptide of claim 170.

The claim as currently written depends from claim 166 which specifies that the peptide is less than 15 amino acids. Thus, claim 170 would encompass the elected peptide fused to a T helper peptide wherein the total length of the fused peptide is 15 amino acids. There is no disclosure in the specification as originally filed of such a peptide. There is no written description of the scope of the claimed invention in the specification as originally filed (e.g. the claimed invention constitutes new matter). This issue can be addressed by amending the claim (using language supported in the specification) to indicate that the fused peptide is of sufficient length to encode a T helper peptide as per the size disclosed in the specification.

11. Regarding priority for the application of prior art, the claimed species of peptide under examination (GVAGALVAFK) is not disclosed in any of the five parent applications to which priority is currently claimed. Regarding "related" applications, "related" is not a claim to priority. While applicant has indicated that the elected peptide species is disclosed in US application 08/103396, there is currently no priority claim to said peptide in the instant application. Therefore, regarding the application of prior art, the priority date is that of the instant application.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

13.. Claims 166,168,170,177,178,180 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubo et al.

Kubo et al. teach the peptide GVAGALVAFK (see page 109). Kubo et al. teach said peptide linked to a T helper epitope (see page 23). Kubo et al. teach pharmaceutical compositions containing said peptide (see page 25) and vaccines containing said peptide (see page 30).

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644